Detailed Action
Summary

This is the Final Office action based on 10/588861 application attorneys remarks filed on 10/30/2009.

Applicant's election with traverse of Claims 1-12 in the reply filed on 07/1/7/2009 is acknowledged. The traversal is on the ground(s) that groups I, II, & III all relate to a single general inventive concept. More specifically, Groups I-III share a special technical feature in the quantification of clinical chemistry analyte, defined as excluding analytes measured using bioaffinity assays in which the analyte is quantified by two-photon excited fluorescence(TPE). In this case the common technical feature is not special. Examiner agrees with applicants argument with respect to MELOTA, however in leiu of SOINI et al. in US 6342397 the restriction is maintained due to the fact that SOINI et al. teach of a biospecific (bioaffinity) assay which uses two-photon excitation (abstract).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are pending and have been fully considered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-10, & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by SOINI et al. in US 6342397.

With respect to Claims 1,2, & 8, SOINI et al. teach of a homogeneous biospecific assay for an analyte in a solution or in a suspension in which the biospecific reagent competitively binding an analyte and a ligand labeled with a fluorescent molecule is reacted with and bound to a solid phase and in which the free labeled ligand is excited with two-photon excitation by focusing the laser-beam suitable for two-photon excitation into the sample volume and the concentration of the analyte is calculated based upon the photo emission contributed by the free labeled ligand(abstract).

With respect to Claim 3, SOINI et al. teach of measuring the reaction kinetically (column 7, line 55-column 8, line 15).

With respect to Claim 4, SOINI et al. teach of making an end point measurement (column 7, line 55-column 8, line 15).

With respect to Claims 5, 6, & 11, SOINI et al. teach of using the method for screening samples and quantifying them as positive or negative for (the method is repeated for different sample to screen them(column 7, lines 48-53). SOINI et al. also teach of using the fluorometric device for the detection of the analyte concentration in which is a protein, antibody, or a nucleotide (abstract, & column 1, lines 17-31).

With respect to Claims 7 & 10, SOINI et al. teach of the analyte being protein (column 1, lines 17-31).

With respect to Claim 12, SOINI et al. teach of determining the concentration of the analyte (quantification of the bioaffinity analytes) (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over SOINI et al. in US 6342397.

With respect to Claim 9, SOINI et al. do not specifically teach of the parameters used for the laser operation. SOINI et al., however does teach that such parameters are optimizable. Specifically, SOINI et al. teach that it is possible to compensate the signal reductions by increasing the average power of the laser correspondingly. The most optimal way to increase the average power is to increase the laser pulse rate (column 3, lines 55-column 4, line 9).

Response to Arguments

Applicant's arguments filed 10/30/2009 have been fully considered but they are not persuasive.

SOINI et al. teach of a homogeneous biospecific assay for an analyte in a solution or in a suspension in which the biospecific reagent competitively binding an

analyte and a ligand labeled with a fluorescent molecule is reacted with and bound to a solid phase and in which the free labeled ligand is excited with two-photon excitation by focusing the laser-beam suitable for two-photon excitation into the sample volume and the concentration of the analyte is calculated based upon the photo emission contributed by the free labeled ligand(abstract).

In response to applicant's arguments, the recitation "clinical chemistry analyte" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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R.F.